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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,716	08/07/2001	Joachim Kramer	AP33451(070180.0144)	1120
21003	7590	12/16/2003	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	20
DATE MAILED: 12/16/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,716

Applicant(s)

KRAMER ET AL.

Examiner

Gary W. Counts

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-- Th MAILING DATE of this communication app ars on th cov r sheet with the corr spondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-26 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 17-26 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 29 and 30 in Paper No. 19 is acknowledged.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if

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the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The disclosure is objected to because of the following informalities: There is no section Entitled **Brief Description OF The Drawings** briefly describing the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29, line 8 the recitation "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

Claim 29 part (b) is vague and indefinite because of the recitation "phosphorylated at positions Y and Z". It is unclear how the peptide or substrate which is phosphorylated in step (a) is again phosphorylated in the Y position. Has the Y position been phosphorylated twice? And if so is this possible?

Claim 29 part (c) "a peptide or protein which is phosphorylated at the Y and Z position" is vague. It is unclear if the antibody is specific for the kinase substrate protein or peptide of part (a) or if it is specific for another peptide or protein phosphorylated at the Y and Z position.

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Claim 29 part (c) is vague and indefinite because it is unclear where the antibody binds? Does it bind to the Y and Z position of the peptide or protein? Or does it bind to the amino acid? Further, if it binds to the amino acid it is unclear if one could determine threonine or serine kinase activity.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al (US 2003/0023990).

Davis et al disclose assays for the detection of inhibitors of protein kinase activity. Davis et al disclose measuring the kinase activity by using ATP and protein substrates in in-vitro assays. Davis et al disclose that JNK protein kinases are activated by dual phosphorylation on Thr and Tyr within protein kinases sub-domain VIII. Davis et al disclose that molecules that inhibit the activation of the kinase by interfering with the phosphorylation of the kinase can be identified by measurement of the kinase activation in the presence and absence of candidate molecules (test compound). Davis et al disclose that the activation of the kinase can be probed using immunological methods

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using antibodies that bind to the Thr and tyr phosphorylated for of the kinase (col p.14, paragraph 0158 to p. 15 paragraph 0165).

It is noted that the instantly recited claims have not clarified the sequence of steps for the phosphorylation of the substrate thus the phosphorylation of the substrate of Davis provides for a substrate phosphorylated at the Y position and therefore reads on the instantly recited claims. Further, it is unclear if the Y position has been phosphorylated once or twice (see 112 rejection above). Therefore, it is the Examiner's position that Davis et al reads on the instantly recited claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (WO 96/36642) in view of Davis et al (US 2003/0023990).

Davis et al (WO 96/36642) disclose methods for identifying reagents which modulates MKK activity, by incubating MKK with the test reagent and ATP and then determining the rate of phosphorylation.

Davis et al differ from the instant invention in failing to teach adding an antibody having specificity to the peptide or protein, which has been phosphorylated, at the Y and Z position.

Davis et al (US 2003/0023990) disclose assays for the detection of inhibitors of protein kinase activity. Davis et al disclose measuring the kinase activity by using ATP and protein substrates in in-vitro assay. Davis et al disclose that the activation of the kinase can be probed using immunological methods using antibodies that bind to the Thr and tyr phosphorylated for of the kinase. Davis et al disclose that the use of these antibodies provides for methods for automated high throughput screens (p. 14 and 15).

It would have been obvious to one of ordinary skill in the art to incorporate antibodies as taught by Davis et al (US 2003/0023990) into the method of Davis et al

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(WO 96/36642) because Davis et al (US 2003/0023990) shows that the use of these antibodies provides for methods for automated high throughput screens.

It is noted that the instantly recited claims have not clarified the sequence of steps for the phosphorylation of the substrate thus the phosphorylation of the substrate of Davis (WO 96/36642) provides for a substrate phosphorylated at the Y position and therefore reads on the instantly recited claims.

Conclusion

11. No claims are allowed.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mosier et al., (Immunoassay Protocol for Quantitation of Protein Kinase Activities, Methods of Enzymology, Vol 305, 2000, pages 410-416). Mosier et al disclose adding ATP and enzyme to determine serine/threonine kinase activity. Mosier et al disclose the use of a synthetic peptide.

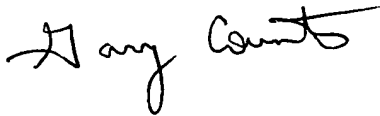
Burke et al., (US 2003/0027236) disclose a method for quantitating enzyme activity of phosphorylation of a peptide or protein substrate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
December 4, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/08/03